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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,096	12/18/2001	Marian L. Kruzel	FDI004	3500

7590 01/13/2004

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/023,096	Applicant(s) KRUZEL, MARIAN L.	
	Examiner Stephen Gucker	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 8-10 and 12 is/are allowed.
- 6) ☒ Claim(s) 4-7 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/27/02
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 4-5 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "naturally occurring [sic] carrier" is found in claims 4 and 11. However, the specification of this divisional application as originally filed does not use the phrase "naturally occurring [sic] carrier" verbatim. The concept of a "naturally occurring [sic] carrier" does not flow from the specification as filed. Applicant argues in the preliminary amendment to declare an interference with U.S. 6,172,040 ("Naidu") that the words "carrier" and "substrate" have identical meaning in the context of their respective disclosures. The carriers for lactoferrin as an antiseptic composition are listed on page 9, lines 7-14 of the instant specification, and they are: saline, silica, talcum, stearic acid, its magnesium or calcium salt, polyethyleneglycol, and fatty emulsions and suspensions. In contrast, the "naturally occurring substrate[s]" of Naidu for a lactoferrin food preservation composition are: proteins, polysaccharides, cellulose, nucleic acids, nucleotides, and lipids. Preferred substrates include collagen,

gelatin, fibronectin, casein, mucin, heparan-sulfate, carrageenan, deoxyribonucleic acid, adenosine triphosphate or a triglyceride, and galactose-rich polysaccharide being most preferred (column 3, lines 22-29). It is the Examiner's position that these two lists are not coincidental enough or overlapping to the degree that the instant application is entitled to use the phrase "naturally occurring [sic] carrier" if such a phrase does not appear in the specification as filed because the concept of a "naturally occurring [sic] carrier" does not readily flow from the instant specification (although the word "carrier" clearly does). Applicant also argues that cellulose is disclosed in the instant application as a naturally occurring substrate or adjuvant or diluent. In fact, cellulose is mentioned in the instant application as "a nutritionally acceptable carrier or adjuvant. Preferred nutritional supplements include tablets, gelatin capsules, or liquids containing the lactoferrin together with adjuvants or diluents, such as lactose, dextrose, sucrose, mannitol, sorbitol, cellulose, and glycine" (page 13, lines 15-17). Although cellulose is mentioned in the Naidu patent, the context is for a naturally occurring carrier for antiseptic compositions. In the instant application, the cellulose is used in the context for a nutritionally acceptable carrier, and not as an antiseptic composition.

This is a new matter rejection. The grounds of this rejection could be obviated by amending the claims to recite a "carrier" or a "nutritionally acceptable carrier" instead of a "naturally occurring [sic] carrier".

2. Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6-7 recite a "recombinant lactoferrin." This phrase is

Art Unit: 1647

indefinite and/or vague because it is not clear what is meant by a "recombinant lactoferrin" as compared to a nonrecombinant lactoferrin because the two lactoferrins in question could be identical in amino acid number and composition and be chemically indistinguishable, one from the other. The Examiner believes that Applicant intended to claim a method that uses lactoferrin which is recombinantly produced, i.e. to specifically identify and claim a method which uses lactoferrin that is produced by genetic engineering rather than lactoferrin isolated from natural sources. The grounds of this rejection could be obviated by amending the claims to read "wherein said lactoferrin is a recombinantly produced lactoferrin."

3. Claims 1-3, 8-10, and 12 are in condition for allowance.

4. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Art Unit: 1647

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

1/7/04

Gary D. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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